



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,698	07/03/2003	Bhiku G. Patel	03-40102-US	7194
<div>7590 07/29/2009</div> <div>William J. McNichol, Jr., Esquire</div> <div>Reed Smith LLP</div> <div>2500 One Liberty Place</div> <div>1650 Market Street</div> <div>Philadelphia, PA 19103-7301</div>				
EXAMINER				
GHALL, ISIS A D				
ART UNIT		PAPER NUMBER		
1611				
MAIL DATE		DELIVERY MODE		
07/29/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte BHIKU G. PATEL, MOHAN VISHNUPAD,
EUGENE H. GANS, and KULJIT S. BHATIA

Appeal 2009-001871¹
Application 10/613,698
Technology Center 1600

Decided: July 29, 2009²

Before DEMETRA J. MILLS, LORA M. GREEN, and
MELANIE L. McCOLLUM, *Administrative Patent Judges*.

McCOLLUM, *Administrative Patent Judge*.

DECISION ON APPEAL

¹ Oral Hearing held June 25, 2009.

² The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the decided date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

This is an appeal under 35 U.S.C. § 134 involving claims to a drug delivery system. The Examiner has rejected the claims as anticipated and/or obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm-in-part.

STATEMENT OF THE CASE

The Specification discloses drug delivery systems that comprise pads, sealed containers, and liquid compositions (Spec. ¶ [1]). In particular, the Specification discloses emulsion compositions including insoluble dermatologically active ingredients (*id.* at ¶ [13]).

The Specification also discloses:

[T]he viscosity of the composition is carefully adjusted to be low enough that the composition will permeate the matrix of the pad's fibers and be held on the pad by capillary action. However, the viscosity must not be so low that the composition is so thin that it drains off the pad prematurely.

(*Id.*) Specifically, the Specification discloses that the “composition of the present invention may be an oil-in-water emulsion with a viscosity of about 500 cps to about 7000 cps, more preferably about 2000 cps to about 3000 cps, and most preferably about 2200 cps” (*id.* at ¶ [27]).

Claims 1-18, 34, and 35 are on appeal. Claims 19 and 21-33 are also pending but have been withdrawn from consideration by the Examiner. (App. Br. 5.) We will focus on claims 1-4, 8, and 15, which read as follows:

1. A drug delivery system comprising
a pad;
a container; and
a liquid composition, wherein the composition comprises: (1) an effective amount of one or more insoluble dermatologically active ingredients, and (2) an emulsion vehicle for the dermatologically active ingredients,

wherein the composition has a viscosity which is low enough for the composition to substantially uniformly absorb onto the pad via capillary action, and high enough to be substantially retained on the pad, not the container.

2. The system of claim 1 wherein the viscosity is effective to substantially uniformly deliver the composition to skin when the pad is wiped on the skin.

3. The system of claim 1 wherein the active ingredient comprises benzoyl peroxide.

4. The system of claim 3 wherein the benzoyl peroxide comprises particles of less than about 50 microns.

8. The system of claim 2 wherein the composition has a viscosity of about 500 to about 9000 cps measured on a Brookfield viscometer LVT model at about 27°C for 60 seconds and a spindle set for 30 rpm.

15. The system of claim 1 wherein the container comprises a material comprised of metal substantially coated with one or more plastics on at least one surface, and one sheet of the material is heat sealed to a second sheet of the material, and the heat sealed materials contain the pad and the composition without leaking.

Claims 1, 2, 6, 7, and 14-18 stand rejected under 35 U.S.C. § 102(b) as anticipated by Smith (US 5,562,642, Oct. 8, 1996) (Ans. 4).

Claims 1, 2, 6, 7, 14, and 16-18 stand rejected under 35 U.S.C. § 102(b) as anticipated by Sine (US 6,183,766 B1, Feb. 6, 2001) (Ans. 4).

Claims 3-5, 8-13, 34, and 35 stand rejected under 35 U.S.C. § 103(a) as obvious over Smith (Ans. 5).

Claims 3-5, 8-13, 34, and 35 stand rejected under 35 U.S.C. § 103(a) as obvious over Sine (Ans. 6).

Claims 4, 5, 34, and 35 stand rejected under 35 U.S.C. § 103(a) as obvious over Smith in view of Sine (Ans. 7).

Claim 15 stands rejected under 35 U.S.C. § 103(a) as obvious over Sine in view of Smith (Ans. 8).

Claims 1-18, 34, and 35 stand rejected under 35 U.S.C. § 103(a) as obvious over Delambre (US 6,784,145 B2, Aug. 31, 2004) in view of Smith (Ans. 9).

Claims 4, 5, 8-12, 34, and 35 stand rejected under 35 U.S.C. § 103(a) as obvious over Smith in view of Delambre (Ans. 10).

Claims 8-12 stand rejected under 35 U.S.C. § 103(a) as obvious over Sine in view of Delambre (Ans. 11).

Claims 1-18, 34, and 35 stand rejected under 35 U.S.C. § 103(a) as obvious over Albacarys (US 6,338,855 B1, Jan. 15, 2002) in view of Smith (Ans. 11).

Claims 4, 5, 8-12, 34, and 35 stand rejected under 35 U.S.C. § 103(a) as obvious over Albacarys in view of Smith and Delambre (Ans. 13).

ANTICIPATION

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros., Inc. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). However, “terms [that] merely set forth the intended use for, or a property inherent in, an otherwise old composition . . . do not differentiate the claimed composition from those known in the prior art.” *In re Pearson*, 494 F.2d 1399, 1403 (CCPA 1974). “Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient to

establish inherency.” *Scaltech Inc. v. Retec/Tetra L.L.C.*, 178 F.3d 1378, 1384 (Fed. Cir. 1999).

SMITH

The Examiner rejects claims 1, 2, 6, 7, and 14-18 as anticipated by Smith (Ans. 4). Appellants argue that Smith fails to teach the viscosity limitation of claim 1 (App. Br. 19-25; Reply Br. 13-14).

Issue

Have Appellants shown that the Examiner erred in concluding that Smith anticipates claim 1?

Findings of Fact

1. Smith discloses a “method for containing, dispensing and applying two or more substances such as solids such as powders or granules, and/or flowable substances such as gels, dispersions or solutions” (Smith, col. 3, l. 66, to col. 4, l. 2).

2. In particular, Smith discloses a “dispensing and applicator system comprising a first and second . . . cover sheet; a first and second applicator pad each . . . being impregnated with a composition comprising a different dermatological agent; and a . . . support sheet” releasably sealed to each of the cover sheets to form first and second compartments containing the first and second pads, respectively (*id.* at col. 4, ll. 6-21).

3. The Examiner finds that Smith “discloses a non-woven pad impregnated by dermatologically active ingredients wherein the non-woven material is capable of absorbing a flowable liquid composition of the active

ingredients (abstract; col.4, lines 37-39; col.5, lines 25-31; col.8, lines 21-34)” (Ans. 4).

4. The Examiner also finds that Smith’s “active ingredients include benzoyl peroxide, which is inherently insoluble . . . (col.10, lines 46-52)” (Ans. 4).

5. In addition, the Examiner finds that Smith discloses a “composition [that] is an emulsion (col.14, lines 38-40; table VI; col.20, lines 15-35)” (Ans. 4). In Table VI, Smith discloses “ingredients [that] were combined . . . to form a moisturizing composition” in the form of an emulsion (Smith, col. 19, l. 48, to col. 20, l. 28).

6. The Examiner also finds that “[v]iscosity is inherent to a specific composition” (Ans. 4).

7. In addition, the Examiner finds:

[S]ince the claims do not recite any specific composition for the emulsion and consequently no amounts, then [Smith] anticipates the claims because it teaches the desired function because it does not teach leakage of the emulsion from the pad to the container and teaches impregnation of the pad with the emulsion composition.

(*Id.* at 14-15.)

8. In particular, the Examiner finds that Smith “recognized the desire to increase the viscosity of the composition to allow retention of the composition into the substrate” (*id.* at 15).

9. In addition, the Examiner finds:

Since the essential elements of the [Smith] composition are identical to the instant compositions, i.e. composition comprising insoluble active agent and emulsion capable to impregnate a pad, then [the Smith] composition has the same

physiochemical properties as the composition set forth in the instant application, such as viscosity of the composition, *depending on the insoluble drug and emulsion composition.*

(*Id.* (emphasis added).)

10. The Examiner also finds that Smith teaches that “materials having viscosities are included in the composition, col.12, lines 54-64, and further teaches semiliquid composition, col.12, lines 6-7. Therefore, the reference implied viscous composition.” (Ans. 15.)

11. Smith discloses that peroxide is “preferably in combination with a gelled or semi-liquid (lotion or cream) vehicle” (Smith, col. 12, ll. 5-8).

Analysis

Claim 1 recites that “the composition has a viscosity which is low enough for the composition to substantially uniformly absorb onto the pad via capillary action, and high enough to be substantially retained on the pad, not the container.” The Examiner argues that Smith “recognized the desire to increase the viscosity of the composition to allow retention of the composition into the substrate” (Finding of Fact (FF) 8). However, as noted by Appellants (App. Br. 24), the Examiner does not clearly indicate where Smith discloses this desire. As noted by the Examiner, Smith does disclose that peroxide is “preferably in combination with a gelled or semi-liquid (lotion or cream) vehicle” (FF 10-11). However, the Examiner does not provide an adequate explanation as to why a gelled or semi-liquid composition would necessarily have the viscosity recited in claim 1.

The Examiner also argues that Smith “anticipates the claims because it teaches the desired function because it does not teach leakage of the

emulsion from the pad to the container and teaches impregnation of the pad with the emulsion composition” (FF 7). However, we do not agree that a disclosure of a pad impregnated with a composition, together with the failure to disclose that the composition leaks from the pad, demonstrates that the broad range of compositions encompassed by Smith all have the viscosity recited in claim 1.

As noted by the Examiner, viscosity is an inherent property of any specific composition (FF 6). However, the Examiner has not set forth a prima facie case that Smith discloses a composition within the scope of claim 1 that inherently has the viscosity recited in claim 1. The Examiner does rely on the composition disclosed in Smith Table VI to show that Smith discloses an emulsion (FF 5). However, even assuming that this composition has the viscosity recited in claim 1, the Examiner has not shown that this composition contains one or more insoluble dermatologically active ingredients, as required by claim 1. Thus, the Examiner has not set forth a prima facie case that this composition anticipates claim 1.

Conclusion

Appellants have shown that the Examiner erred in concluding that Smith anticipates claim 1. We therefore reverse the anticipation rejection over Smith of claim 1 and of claims 2, 6, 7, and 14-18, which depend from claim 1.

SINE

The Examiner rejects claims 1, 2, 6, 7, 14, and 16-18 as anticipated by Sine (Ans. 4). Appellants argue that Sine fails to teach the viscosity limitation of claim 1 (App. Br. 25-27; Reply Br. 14-15).

Issue

Have Appellants shown that the Examiner erred in concluding that Sine anticipates claim 1?

Findings of Fact

12. Sine discloses “compositions for sanitizing and moisturizing skin surfaces” comprising a sanitizing agent, a lipophilic skin moisturizing agent, and a degreasing agent (Sine, Abstract).

13. Sine also discloses that the compositions are preferably “emulsions which comprise a moisturizing phase,” the “moisturizing phase provid[ing] the vehicle for delivering the lipophilic skin moisturizing agents to the skin of the user” (*id.* at col. 4, ll. 17-23).

14. In addition, Sine discloses that, “[o]ptionally, the lipophilic skin moisturizing agent can be thickened using a thickening agent” and lists suitable thickening agents (*id.* at col. 4, ll. 33-43).

15. Sine also discloses that the compositions “can also, optionally, contain antimicrobial agents” and lists benzoyl peroxide as an example of an antimicrobial agent (*id.* at col. 12, ll. 6-56).

16. In addition, Sine discloses that the compositions “can also be, optionally, incorporated into a[n] insoluble substrate for application to the skin such as in the form of a treated wipe” (*id.* at col. 16, ll. 33-35).

17. Sine also discloses “an article of manufacture comprising a dispensing container containing the moisturizing and sanitizing composition” (*id.* at col. 17, ll. 41-43).

18. The Examiner finds that “[v]iscosity is inherent to a specific composition” (Ans. 5).

19. The Examiner also finds:

[S]ince the claims do not recite any specific composition for the emulsion and consequently no amounts, then [Sine] anticipates the claims because it teaches the desired function because it does not teach leakage of the emulsion from the pad to the container and teaches impregnation of the pad with the emulsion composition.

(*Id.* at 17.)

20. In addition, the Examiner finds that Sine “recognized the desire to increase the viscosity of the composition to allow retention of the composition into the substrate (col.4, lines 33-37)” (Ans. 17).

21. The Examiner also finds:

Since the essential elements of the [Sine] composition are identical to the instant compositions, i.e. composition comprising insoluble active agent and emulsion, then [the Sine] composition has the same physiochemical properties as the composition set forth in the instant application, such as viscosity of the composition, *depending on the insoluble drug and the emulsion composition.*

(*Id.* at 17-18 (emphasis added).)

22. In addition, the Examiner finds that Sine teaches that “materials having viscosities are included in the composition, col.6, lines 30-50. Therefore, the reference implied viscous composition.” (Ans. 18.)

Analysis

As noted by the Examiner, viscosity is an inherent property of a specific composition (FF 18). However, the Examiner has not set forth a prima facie case that Sine discloses a composition that inherently has the viscosity recited in claim 1.

In particular, the Examiner argues that Sine “recognized the desire to increase the viscosity of the composition to allow retention of the composition into the substrate” (FF 20). In support of this position, the Examiner relies on the disclosure in Sine that “the lipophilic skin moisturizing agent can be thickened using a thickening agent” (FF 14 & 20). However, we agree with Appellants (App. Br. 26 (citing App. Br. 21-23)) that, depending on the amount of thickening agent, as well as the viscosity of the other components in the composition, a composition containing a thickening agent could or could not have the viscosity recited in claim 1, that is, “a viscosity which is low enough for the composition to substantially uniformly absorb onto the pad via capillary action, and high enough to be substantially retained on the pad, not the container.”

The Examiner also argues that Sine “anticipates the claims because it teaches the desired function because it does not teach leakage of the emulsion from the pad to the container and teaches impregnation of the pad with the emulsion composition” (FF 19). However, we do not agree that a disclosure of a pad impregnated with a composition, together with the failure to disclose that the composition leaks from the pad, demonstrates that Sine’s compositions necessarily have the viscosity recited in claim 1. Therefore,

we cannot agree that the Examiner has set forth a *prima facie* case that Sine anticipates claim 1.

Conclusion

Appellants have shown that the Examiner erred in concluding that Sine anticipates claim 1. We therefore reverse the anticipation rejection over Sine of claim 1 and claims 2, 6, 7, 14, and 16-18, which depend from claim 1.

OBVIOUSNESS

“In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a *prima facie* case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant.” *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993) (citation omitted).

[I]t is elementary that the mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to those things to distinguish over the prior art. Additionally, where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.

In re Best, 562 F.2d 1252, 1254-55 (CCPA 1977) (quoting *In re Swinehart*, 439 F.2d 210, 212-13 (CCPA 1971)).

“[T]he discovery of an optimum value of a variable in a known process is normally obvious.” *In re Antonie*, 559 F.2d 618, 620 (CCPA

1977). However, exceptions to this rule include (1) the results of optimizing a variable were unexpectedly good and (2) the parameter optimized was not recognized in the prior art as one which would affect the results. *Id.*

“[L]ong-felt need is analyzed as of the date of an articulated identified problem and evidence of efforts to solve that problem.” *Texas Instruments, Inc. v. International Trade Comm.*, 988 F.2d 1165, 1178 (Fed. Cir. 1993).

“[I]t is well settled that unexpected results must be established by factual evidence. ‘Mere argument or conclusory statements in the specification does not suffice.’” *In re Geisler*, 116 F.3d 1465, 1470 (Fed. Cir. 1997) (quoting *In re De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984)).

“An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness.” *In re Geisler*, 116 F.3d at 1470.

SMITH, ALONE OR IN VIEW OF SINE

The Examiner rejects claims 3-5, 8-13, 34, and 35 as obvious over Smith (Ans. 5). The Examiner also rejects claims 4, 5, 34, and 35 as obvious over Smith in view of Sine (*id.* at 7).

Appellants argue that Smith does not teach or suggest the viscosity limitation of claim 1, from which these claims depend (App. Br. 28-30; Reply Br. 16-17). Appellants also argue that they have refuted any prima facie case of obviousness with a showing of long felt need and unexpected results (App. Br. 31; Reply Br. 17-18). In addition, Appellants argue that Smith does not disclose the viscosities recited in claims 8-12 (App. Br. 32; Reply Br. 19).

Appellants also argue that Smith does not disclose the particle sizes recited in claims 4, 5, 34, and 35 (App. Br. 32; Reply Br. 18-19). In addition, Appellants argue that Sine also fails to disclose the particle sizes recited in claims 4, 5, 34, and 35 (App. Br. 38-42; Reply Br. 23).

Issues

Have Appellants shown that the Examiner erred in concluding that claim 3 would have been obvious over Smith?

Have Appellants shown that the Examiner erred in concluding that claims 8-12 would have been obvious over Smith?

Have Appellants shown that the Examiner erred in concluding that claims 4, 5, 34, and 35 would have been obvious over Smith, alone or in view of Sine?

Findings of Fact

23. The Specification discloses it is desirable to have “dermatologically active ingredients placed on pads for delivery by wiping the pad on the skin. . . . However, several problems exist with this approach when it is applied to dermatologically active ingredients that are insoluble, minimally or weakly soluble.” (Spec. ¶ [3].)

24. The Specification also discloses:

Factors that are relevant to these problems include, that a portion of the liquid composition may preferentially squeeze through the fibers of the pad, leaving a high concentration of particulate dermatologically active ingredients on a surface of the pad. On the other hand, dermatologically active ingredient particles may preferentially squeeze through the fibers and leave particles on the walls of the container or in some parts of the pad or container, but not others.

(*Id.* at ¶ [5].)

25. In addition, the Specification discloses:

The present invention overcomes many of the problems experienced in the art. In this invention, the . . . composition is retained by the pad preferentially over the container. Dermatologically active ingredients, e.g. without limitation, BPO [benzoyl peroxide], and insoluble antifungals, do not preferentially migrate or adsorb from the composition (e.g. without limitation, emulsion) onto or into the pad, and therefore does not result in an uneven concentration of the dermatologically active ingredient in the composition versus the pad.

(*Id.* at ¶ [11].)

26. The Examiner finds that Smith “suggests the use of BPO for skin application from a pad and also suggests the emulsion” (Ans. 5).

27. The Examiner concludes:

[O]ne having ordinary skill in the art at the time of the invention would have been motivated to include BPO in the emulsion of table VI, motivated by the skill of versed artisan that BPO is effective to treat acne, with reasonable expectation of having emulsion comprising BPO impregnated into a pad wherein the emulsion is delivered cutaneously and effective against acne.

(*Id.*)

28. The Examiner also concludes:

[T]he burden is on applicants to show that the functions of the claimed composition resulted in novel and unobvious difference between the claimed product and prior art product since the Patent Office does not have the facilities for preparing and measuring the claimed viscosities and comparing them with the prior art inventions.

(*Id.* at 20.)

29. In addition, the Examiner finds that the “claimed particle sizes . . . do not impart patentability to the claims, absent evidence to the contrary” (*id.* at 5).

30. The Examiner concludes that it would have been obvious “to select the particle sizes, since the art teaches using granules or powders, and implies retention of the granules or particles in the applicator see col. 8, lines 34-35” (Ans. 20-21). In discussing applicator pads, Smith discloses “a sheet of plastic or stiff paper having pores through which a powder or granular substance, or flowable substance, may be dispensed” (Smith, col. 8, ll. 25-34).

31. The Examiner also finds that “the particle sizes are result effective variables because changing them will clearly affect the type of product obtained” and that “[c]ase law holds that ‘discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art.’ See *In re Boesch*, 617 F.2d 272 . . . (CCPA 1980).” (Ans. 21.)

32. Alternatively, the Examiner finds that Sine teaches that “particle[] sizes of the emulsion are preferred to be between 0.2 and 200 micron[s]” (*id.* at 7).

33. Sine discloses that the “average droplet size of the moisturizing phase droplets, which comprise the lipophilic skin moisturizing agent, ranges from about 0.005 microns to about 1000 microns, preferably from about 0.1 to about 500 microns, and more preferably from about 0.2 to about 200 microns in diameter” (Sine, col. 4, ll. 23-28).

Analysis

Smith discloses an applicator pad impregnated with an emulsion, the pad being in a container (FF 1-3 & 5). Appellants do not dispute the Examiner's conclusion that it would have been obvious "to include BPO in the emulsion of table VI" (FF 27). Although the viscosity of the resulting composition is not disclosed, the resulting composition meets the other requirements of the liquid composition of claim 1. In these circumstances, we conclude that it was appropriate for the Examiner to shift the burden to Appellants to show that the resulting composition would not have the viscosity recited in claim 1 (FF 28).

Appellants argue that the general teachings of Smith would not necessarily result in the viscosity recited in claim 1 (App. Br. 28-30). However, Appellants do not address the emulsion of table VI modified to include BPO. Thus, Appellants have not shown that the Examiner erred in concluding that claim 3 would have been *prima facie* obvious.

Appellants also argue that they have "overcome the problems in the prior art and ha[ve] satisfied the long felt need for a pad delivery system for insoluble dermatologically active ingredients" (App. Br. 31). In particular, Appellants argue:

[P]rior to the present invention, pad delivery systems for particulate therapeutic agents have posed serious problems. The pads in the prior art often act to filter out the particles from the liquid and retain the particles on the pad matrix resulting in sub-optimal or even sub-therapeutic delivery of the agents. Further, the prior art had problems with the retention of the composition with the particulate therapeutic agent in the pad and release of the composition with the dermatologically active ingredient from the pad. This problem is compounded further

when the pad or cloth is stored in a pouch or similar container. Without the viscosity of the present invention, the composition adheres to the walls of the container making the composition unavailable or only minimally available for its intended use.

(*Id.*) Appellants also argue that an unexpected result has been proven (Reply Br. 18).

We are not persuaded. The Specification discloses that it is desirable to have “dermatologically active ingredients placed on pads for delivery by wiping the pad on the skin,” but that “several problems exist with this approach when it is applied to dermatologically active ingredients that are insoluble, minimally or weakly soluble” (FF 23-24). The Specification also states that the “present invention overcomes many of the problems experienced in the art” (FF 25). However, Appellants have not provided sufficient evidence to demonstrate that the system of claim 3 resolved a long-felt need or provides unexpectedly superior properties. In particular, Appellants have not provided evidence that this need was articulated before the time of the present invention or evidence of efforts to solve the problem. In addition, Appellants have not provided sufficient factual evidence to prove unexpected results.

With regard to claims 8-12, Appellants argue that Smith “does not disclose the [claimed] viscosities” (App. Br. 32). In addition, Appellants argue that, “even if a *prima facie* case of obviousness was established, long felt need and unexpected result . . . have been proven overcoming the rejection” (Reply Br. 19). We are not persuaded.

For the reasons discussed above, we find that it was appropriate for the Examiner to shift the burden to Appellants to show that the resulting

composition would not have the viscosities recited in claims 8-12 (FF 28). Appellants argue that Smith “fails to even mention the viscosity, much less the specific ranges called for by claims 8-12” (App. Br. 32). However, Appellants do not address the emulsion of table VI modified to include BPO. Thus, Appellants have not shown that the Examiner erred in concluding that claim 8-12 would have been *prima facie* obvious. In addition, we do not agree that Appellants have provided sufficient evidence of long-felt need or unexpected results for the reasons discussed above.

With regard to claims 4, 5, 34, and 35, Appellants additionally argue that Smith “does not disclose the [claimed] active ingredient particle sizes” (App. Br. 32). Appellants also argue the Sine does not overcome this deficiency (App. Br. 38-41). We agree.

As noted by the Examiner, Smith discloses powders and granules and that the applicator pad has pores through which a powder or granule may be dispensed (FF 1 & 30). However, we do not agree that these teachings are sufficient to suggest including, in a liquid composition, an insoluble dermatologically active ingredient having the claimed particle sizes. In addition, as noted by Appellants (Reply Br. 18), the Examiner has not shown that particle size was recognized in the prior art as a result effective variable.

Furthermore, Sine discloses that the “average droplet size of the moisturizing phase droplets, which comprise the lipophilic skin moisturizing agent, ranges from about 0.005 microns to about 1000 microns, preferably from about 0.1 to about 500 microns, and more preferably from about 0.2 to about 200 microns in diameter” (FF 33). However, we agree with Appellants that this disclosure does not teach or suggest that the insoluble

dermatologically active ingredient, specifically benzoyl peroxide, should have a particle size of 0.2 to 200 microns, as alleged by the Examiner (Ans. 7-8). Thus, the Examiner has not set forth a prima facie case that claims 4, 5, 34, and 35 would have been obvious over Smith, alone or in view of Sine.

Conclusion

Appellants have not shown that the Examiner erred in concluding that claim 3 would have been obvious over Smith. We therefore affirm the obviousness rejection of claim 3 over Smith. Claim 13 has not been argued separately and therefore falls with claim 3. 37 C.F.R. § 41.37(c)(1)(vii).

Appellants also have not shown that the Examiner erred in concluding that claims 8-12 would have been obvious over Smith. We therefore also affirm the obviousness rejection of these claims over Smith.

However, Appellants have shown that the Examiner erred in concluding that claims 4, 5, 34, and 35 would have been obvious over Smith, alone or in view of Sine. We therefore reverse the obviousness rejections of these claims over Smith, alone or in view of Sine.

SINE

The Examiner rejects claims 3-5, 8-13, 34, and 35 as obvious over Sine (Ans. 6).

Appellants argue that Sine does not teach or suggest the viscosity limitation of claim 1, from which these claims depend (App. Br. 33-36; Reply Br. 20-21).

Issue

Have Appellants shown that the Examiner erred in concluding that Sine teaches or suggest the viscosity recited in claim 1?

Findings of Fact

34. The Examiner finds that Sine “teaches [that] materials having viscosities are included in the composition. . . . Therefore, the reference implied viscous composition.” (Ans. 22.)

35. The Examiner concludes that it would have been obvious to “adjust the viscosity motivated by the desire of the reference to obtain viscous fluid to be absorbed into the pad” (*id.* at 7).

Analysis

Sine discloses compositions comprising a thickening agent (FF 14). Sine also discloses that its compositions can be “incorporated into a[n] insoluble substrate for application to the skin such as in the form of a treated wipe” (FF 16). The Examiner concludes that it would have been obvious to “adjust the viscosity motivated by the desire of the reference to obtain viscous fluid to be absorbed into the pad” (FF 35).

We do not agree that the Examiner has set forth a *prima facie* case that it would have been obvious to adjust the viscosity in order to provide a composition having a viscosity that is low enough for the composition to substantially uniformly absorb onto a pad via capillary action and high enough to be substantially retained on the pad, not the container. In particular, the Examiner has not shown that Sine discloses a desire to obtain fluid having a viscosity that is low enough for the composition to substantially uniformly absorb onto the pad via capillary action, nor has the

Examiner shown that Sine discloses adjusting the viscosity to provide a composition that is substantially retained on the pad, not the container.

Conclusion

Appellants have shown that the Examiner erred in concluding that Sine teaches or suggest the viscosity recited in claim 1. We therefore reverse the obviousness rejection over Sine of claims 3-5, 8-13, 34, and 35, which depend from claim 1.

SINE IN VIEW OF SMITH

The Examiner rejects claim 15 as obvious over Sine in view of Smith (Ans. 8). Claim 15 depends from claim 1. The Examiner relies on Sine for disclosing the viscosity of claim 1 (*id.*). The Examiner relies on Smith for disclosing the package of claim 15 (*id.*). In the context of this rejection, the Examiner does not rely on Smith for disclosing the viscosity of claim 1 (*id.* at 8-9).

As discussed above, we agree with Appellants that the Examiner has not set forth a prima facie case that Sine discloses or suggest the viscosity of claim 1. For the same reasons, we agree with Appellants that the Examiner has not set forth a prima facie case that claim 15 would have been obvious over Sine in view of Smith. We therefore reverse the obviousness rejection of claim 15 over Sine in view of Smith.

DELAMBRE IN VIEW OF SMITH

The Examiner rejects claims 1-18, 34, and 35 as obvious over Delambre in view of Smith (Ans. 9).

Appellants argue that Delambre “teaches a composition having a viscosity below 150 mPa.s” and that this “viscosity is well below the range of the claimed invention” (App. Br. 44). Appellants also argue that “long felt need and unexpected result . . . have been proven overcoming this rejection” (Reply Br. 26). In addition, Appellants argue that Delambre and Smith “do not teach the limitations of claim 2,” the particles sizes recited in claims 4, 5, 34, and 35, and the viscosities recited in claims 8-12 (App. Br. 45-46).

Issues

Have Appellants shown that the Examiner erred in concluding that Delambre teaches compositions having a viscosity that is high enough to be substantially retained on the pad, not the container?

Have Appellants shown that the Examiner erred in concluding that Appellants did not provide sufficient evidence to rebut a prima facie case that claim 1 would have been obvious over Delambre and Smith?

Have Appellants shown that the Examiner erred in concluding that claim 2 would have been obvious over Delambre and Smith?

Have Appellants shown that the Examiner erred in concluding that claims 4, 5, 34, and 35 would have been obvious over Delambre and Smith?

Have Appellants shown that the Examiner erred in concluding that claims 8-12 would have been obvious over Delambre and Smith?

Findings of Fact

36. The Specification discloses that “the viscosity must not be so low that the composition is so thin that it drains off the pad prematurely” (Spec. ¶ [13]).

37. The Specification also discloses that “[u]se of the present invention by wiping the pad across skin results in a transfer to the skin of the dermatologically active ingredient, meaning that the skin is substantially uniformly medicated” (*id.* at ¶ [14]).

38. In addition, the Specification discloses that the “composition of the present invention may be an oil-in-water emulsion with a viscosity of about 500 cps to about 7000 cps” (*id.* at ¶ [27]).

39. Delambre “relates to an article, preferably a wipe, comprising (A) a water-insoluble substrate, and (B) a composition added to, impregnated onto, in contact with, etc. the substrate comprising an aqueous phase and N-(3-chloroallyl)hexaminium chloride” (Delambre, col. 1, ll. 8-13).

40. Delambre discloses that “the composition intended to contact, impregnate, etc. a support has a viscosity that is preferably less than 150 mPa.s and more preferably less than 100 mPa.s. This viscosity preferably ranges from 1 mPa.s to 100 mPa.s.” (*Id.* at col. 3, ll. 23-26.)

41. Delambre also discloses that the composition may be in the form of an emulsion (*id.* at col. 3, ll. 33-41).

42. In addition, Delambre discloses that the composition may include active agents, such as benzoyl peroxide (*id.* at col. 6, ll. 31-39).

43. Delambre also discloses using emulsion forming techniques that provide “‘ultrafine’ O/W emulsions, in which the mean size of the globules constituting the fatty phase is within well-defined limits, i.e. between 50 and 1000 nm” (which is between 0.05 and 1 micron) and that these “emulsions are extremely fluid and are particularly suitable for

impregnating water-insoluble substrates so as to constitute cleaning articles or wipes” (*id.* at col. 7, ll. 62-68).

44. The Examiner finds that Delambre “recognized that the suitable sizes of the particles to be delivered to the skin from a pad impregnated with an emulsion is between 50 and 1000 micron and also teaches that the emulsion droplets having such sizes are suitable for impregnation in the substrate” (Ans. 28).

45. The Examiner concludes that “one having ordinary skill in the art would have provided any particles within that range to be certain of its impregnation into the substrate and its delivery through the skin pores” (*id.*).

46. The Examiner also finds that “the particle sizes are result effective variables because changing them will clearly affect the type of product obtained” and that “[c]ase law holds that ‘discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art.’ See *In re Boesch*, 617 F.2d 272 . . . (CCPA 1980).” (Ans. 28-29.)

47. The Examiner relies on Smith for teaching “a container for substrate impregnated with a liquid composition” (*id.* at 9).

48. In the context of this rejection, the Examiner does not rely on Smith for disclosing the viscosity of claim 1 (*id.* at 9-10).

Analysis

The Specification discloses that the “composition is retained by the pad preferentially over the container” (FF 25). The Specification also discloses that “the viscosity must not be so low that the composition is so thin that it drains off the pad prematurely” (FF 36). In addition, the

Specification discloses that the “composition of the present invention may be an oil-in-water emulsion with a viscosity of about 500 cps to about 7000 cps” (FF 38). However, the Specification does not provide any additional guidance as to the minimum viscosity required for the composition to be substantially retained on the pad, not the container.

Delambre discloses that the viscosity of the composition “is preferably less than 150 mPa.s and more preferably less than 100 mPa.s,” and “preferably ranges from 1 mPa.s to 100 mPa.s” (FF 40). Delambre does not state that this viscosity is high enough to be substantially retained on the pad, not the container. However, Delambre does disclose impregnating its composition onto a substrate, such as a wipe (FF 39). In these circumstances, we find that it was appropriate for the Examiner to shift the burden to Appellants to show that compositions having a viscosity within the range recited in Delambre are not substantially retained on the pad.

Appellants present attorney argument indicating that the “viscosity taught in [Delambre] is significantly below that of the claimed invention” and “would result in the active ingredient being filtered by the pad and not being applied to the treatment site” (App. Br. 44). However, Appellants have not provided sufficient evidence that the viscosities recited in Delambre are not high enough for the composition to be substantially retained on the pad, not the container. Therefore, we are not persuaded by Appellants’ arguments to the contrary. In addition, Appellants have not provided sufficient evidence of long felt need or unexpected results for the reasons discussed above.

Appellants also argue that Delambre and Smith “fail to disclose or suggest a viscosity effective to substantially uniformly deliver the composition to skin when the pad is wiped on the skin” (App. Br. 45). The Specification discloses that “[u]se of the present invention by wiping the pad across skin results in a transfer to the skin of the dermatologically active ingredient, meaning that the skin is substantially uniformly medicated” (FF 37). Thus, for the same reasons that we conclude that it was appropriate for the Examiner to shift the burden to Appellants to show that Delambre does not disclose a composition having the viscosity of claim 1, we conclude that it was appropriate for the Examiner to shift the burden to Appellants to show that Delambre does not disclose a composition having the viscosity of claim 2. Appellants have not provided sufficient evidence that Delambre does not disclose such a viscosity.

With regard to claims 4, 5, 34, and 35, Appellants additionally argue that Delambre “fails to teach the [claimed] active ingredient particle sizes” (App. Br. 46). We agree.

Delambre discloses using emulsion forming techniques that provide “‘ultrafine’ O/W emulsions, in which the mean size of the globules constituting the fatty phase is within well-defined limits, i.e. between 50 and 1000 nm” (which is between 0.05 and 1 micron) and that these “emulsions are extremely fluid and are particularly suitable for impregnating water-insoluble substrates so as to constitute cleaning articles or wipes” (FF 43). However, we agree with Appellants that this disclosure does not teach or suggest that the insoluble dermatologically active ingredient, specifically benzoyl peroxide, should have a particle size between 0.05 and 1 micron.

We recognize the Examiner's argument that "one having ordinary skill in the art would have provided any particles within that range to be certain of its impregnation in the substrate and its delivery through the skin pores" (FF 45). However, Delambre does not disclose the size of insoluble dermatological active ingredients, but of fatty phase globules (FF 43). We do not agree that a disclosure of fatty phase globules in a particular size range necessarily implies that insoluble dermatologically active agents should also be in that size range.

With regard to claims 8-12, Appellants argue that Delambre does not disclose or suggest the claimed viscosities (App. Br. 46). We agree.

As discussed above, Delambre discloses that the composition "has a viscosity that is preferably less than 150 mPa.s" (FF 40). The Examiner has not provided an adequate explanation as to why one of ordinary skill in the art would have modified Delambre's compositions to provide a composition having a viscosity of at least about 500 cps (i.e., 500 mPa.s), as recited in claims 8-12.

Conclusion

Appellants have not shown that the Examiner erred in concluding that Delambre teaches compositions having a viscosity that is high enough to be substantially retained on the pad, not the container. Appellants also have not shown that the Examiner erred in concluding that Appellants did not provide sufficient evidence to rebut a prima facie case that claim 1 would have been obvious. We therefore affirm the obviousness rejection over Delambre and Smith of claim 1. Claims 3, 6, 7, and 13-18 have not been argued separately and therefore fall with claim 1. 37 C.F.R. § 41.37(c)(1)(vii).

Appellants also have not shown that the Examiner erred in concluding that claim 2 would have been obvious over Delambre and Smith. We therefore also affirm the obviousness rejection over Delambre and Smith of claim 2.

However, Appellants have shown that the Examiner erred in concluding that claims 4, 5, 8-12, 34, and 35 would have been obvious over Delambre and Smith. We therefore reverse the obviousness rejection over Delambre and Smith of these claims.

SMITH OR SINE IN VIEW OF DELAMBRE

The Examiner rejects claims 4, 5, 8-12, 34, and 35 as obvious over Smith in view of Delambre (Ans. 10). The Examiner also rejects claims 8-12 as obvious over Sine in view of Delambre (*id.* at 11).

We are affirming the obviousness rejection of claims 8-12 over Smith alone. For the same reasons, we affirm the obviousness rejection of claims 8-12 over Smith in view of Delambre.

We conclude above that the Examiner has not set forth a *prima facie* case that claims 4, 5, 34, and 35 would have been obvious over Smith alone. We also conclude above that the Examiner has not set forth a *prima facie* case that Delambre teaches or suggests the features of claims 4, 5, 34, and 35. For these reasons, we also reverse the rejection of claims 4, 5, 34, and 35 over Smith in view of Delambre.

In addition, we conclude above that the Examiner has not set forth a *prima facie* case that claims 8-12 would have been obvious over Sine alone. We also conclude above that the Examiner has not set forth a *prima facie*

case that Delambre teaches or suggests the features of claims 8-12. For these reasons, we also reverse the rejection of claims 8-12 over Sine in view of Delambre.

ALBACARYS IN VIEW OF SMITH AND/OR DELAMBRE

The Examiner rejects claims 1-18, 34, and 35 as obvious over Albacarys in view of Smith (Ans. 11). The Examiner also rejects claims 4, 5, 8-12, 34, and 35 as obvious over Albacarys in view of Smith and Delambre (*id.* at 13).

Appellants argue that Albacarys does not teach or suggest the viscosity limitation of claim 1 and that neither Smith nor Delambre overcomes the deficiencies of Albacarys (App. Br. 52-53).

Issue

Have Appellants shown that the Examiner erred in concluding that Albacarys, in view of Smith and/or Delambre, discloses or suggests a composition having the viscosity of claim 1?

Findings of Fact

49. Albacarys discloses “disposable, single use personal care cleansing and conditioning articles comprising (A) a water insoluble substrate, (B) at least one lathering surfactant . . . , and (C) a skin care component” (Albacarys, col. 3, ll. 25-29).

50. Albacarys also discloses that the “products of the present invention effectively and efficiently deliver skin care actives to the skin and hair by maintaining the skin care actives substantially on the surface of the substrate” (Albacarys, col. 47, ll. 53-56).

51. In addition, Albacarys discloses that the “term ‘chemical component,’ as used herein, means the skin care active or a combination of the conditioning agent and the skin care active” (*id.* at col. 47, ll. 62-64).

52. Albacarys also discloses that one “method of substantially maintaining the chemical component on the surface of the substrate is by increasing the viscosity before application onto the substrate” (*id.* at col. 48, ll. 52-54).

53. In particular, Albacarys discloses:

If the chemical component is a liquid at room temperature (e.g., not viscous), the chemical component will not remain primarily on the surface of the substrate. Instead, the chemical component will tend to migrate and flow into the void volume of the substrate. The present method provides a solution by introducing a thickening agent into the chemical component. This increases the viscosity of the chemical component. . . . Because the viscosity of the chemical component is effectively increased, it remains substantially on the surface of the substrate without saturating the substrate. Generally, the thickening agent must be viscous at room temperature, and it must be miscible with the chemical component.

(*Id.* at col. 49, ll. 35-48.)

54. The Examiner finds that the “viscosity do[es] not impart patentability to the claims because the art recognized the desire to have viscosity of the impregnated composition enough to retain the composition in the pad, absent evidence to the contrary” (Ans. 12).

55. The Examiner relies on Smith for teaching “a container for substrate impregnated with a liquid composition” (*id.*).

56. In the context of these rejections, the Examiner does not rely on Smith for disclosing the viscosity of claim 1 (*id.* at 11-14).

57. The Examiner relies on Delambre for features of dependent claims (*id.* at 13).

Analysis

Albacarys discloses compositions comprising a thickening agent (FF 53). In particular, Albacarys discloses a composition that, because of its viscosity, “remains substantially on the surface of the substrate without saturating the substrate” (*id.*). The Examiner has not adequately explained why such a composition would inherently have a viscosity that is low enough for the composition to substantially uniformly absorb onto a pad via capillary action and high enough to be substantially retained on the pad, not the container, or why it would have been obvious based on the disclosures in Smith or Delambre to modify Albacarys’ composition to have such a viscosity.

Conclusion

Appellants have shown that the Examiner erred in concluding that Albacarys, in view of Smith and/or Delambre, discloses or suggests a composition having the viscosity of claim 1. We therefore reverse the rejections over Albacarys in view of Smith and/or Delambre of claim 1 and of claims 2-18, 34, and 35, which depend from claim 1.

SUMMARY

We affirm the obviousness rejections of claims 3 and 8-13 over Smith; of claims 1-3, 6, 7, and 13-18 over Delambre in view of Smith; and of claims 8-12 over Smith in view of Delambre.

We reverse the anticipation rejections. We also reverse the obviousness rejections of claims 4, 5, 34, and 35 over Smith, alone or in view of Sine or Delambre; of claims 3-5, 8-13, 15, 34, and 35 over Sine, alone or in view of Smith or Delambre; of claims 4, 5, 8-12, 34, and 35 over Delambre in view of Smith; and of claims 1-18, 34, and 35 over Albacarys in view of Smith and/or Delambre. Thus, claims 4, 5, 34, and 35 are not currently subject to a rejection.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART

alw

WILLIAM J. McNICHOL, JR., ESQUIRE
REED SMITH LLP
2500 ONE LIBERTY PLACE
1650 MARKET STREET
PHILADELPHIA, PA 19103-7301